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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,008	03/24/2004	Roger Cady	57294.019	5678

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EXAMINER	
KAM, CHIH MIN	

ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 05/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/808,008	CADY, ROGER	
	Examiner	Art Unit	
	Chih-Min Kam	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16 and 22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 16 and 22 are pending.

Applicants' amendment filed on March 7, 2006 is acknowledged. Applicants' response has been fully considered. Claim 24 has been cancelled, and claim 22 has been amended. Therefore, claims 16 and 22 are examined.

Withdrawn Claim Rejections - 35 USC § 112

2. The previous rejection of claim 22 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicant's amendment to the claims, and applicant's response at page 4 in the amendment filed March 7, 2006.

Maintained Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 16 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donovan (US 2004/0009180).

Donovan teaches a pharmaceutical composition containing a botulinum toxin (e.g., botulinum toxin type A) and at least one enhancing agent for facilitating transdermal delivery of the botulinum toxin into a human patient (paragraph [0056]), wherein the pharmaceutical composition can be used to treat several types of disorders associated with neurotransmitter release (e.g., migraine, fibromyalgia or neurogenic inflammation; paragraphs [0043] and [0066]),

and wherein the botulinum toxin can be lyophilized, reconstituted with saline or water, and an enhancing agent can be added to the composition (paragraphs [0069]-[0073]), where the enhancing agent refers to an agent that enhances the permeability of the patient's skin so that botulinum toxin can be absorbed by the skin to achieve a therapeutic effect, e.g., lecithin vesicles, and the enhancing agent excludes the combination of pluronic lecithin organogel (PLO) and DMSO (paragraph [0050]). The reference also indicates botulinum toxin may act on the sensory neurons to decrease the release of substance P or CGRP (calcitonin gene-related peptide) to reduce inflammation and pain associated with inflammation (paragraph [0085]). Although the reference does not specifically recite the use of PLO as enhancing agent, it indicates the enhancing agent may include, and is not limited to alcohols, surfactants, lecithin vesicles and others. Furthermore, it does not exclude the use of PLO alone (paragraph [0050]). At the time of invention was made, it would have been obvious that one of ordinary skill in the art is motivated to use a pharmaceutical composition containing botulinum toxin type A, saline and PLO as an enhancing agent for the treatment of migraine (claim 16) and inhibiting the release of neurotransmitter in trigeminal neurons to treat symptoms of migraine (claim 22) because PLO is a known topical and transdermal carrier (see Art of Record in previous Office Action dated 12/7/05), which can enhance the permeability of the patient's skin so that botulinum toxin can be absorbed by the skin to achieve a therapeutic effect. Therefore, in view of the teachings of Donovan and the art with respect to the use of PLO as a transdermal carrier, it would have been obvious to use a pharmaceutical composition containing botulinum toxin type A, saline and PLO as an enhancing agent for the treatment of migraine and inhibiting the release of neurotransmitter

in trigeminal neurons to treat symptoms of migraine, which result in the claimed invention and was, as a whole, prima facie obvious at the time the claimed invention was made.

Response to Arguments

Applicant indicates while Donovan makes reference to lecithin vesicles as possible enhancing agents, the only reference it makes to pluronic lecithin organogel (PLO) is to expressly exclude it in combination with dimethylsulfoxide (DMSO). PLOs have been relatively recently developed and incorporate a synthetic polymer that acts as cosurfactant and stabilizer. While Donovan provides an extensive list of suitable enhancing agents, including lecithin vesicles, it does not include PLOs within that list and, further only references PLOs in an exclusionary statement. The incorporation of pluronics to form PLOs is not chemically insignificant as it changes the basic nature not only of the overall composition but of the quality of lecithin used in the composition. Thus, taken together, Donovan actually teaches away from the use of PLOs (pages 4-5 of the response).

Applicant's response has been considered, however, the arguments are not found persuasive because of the following reasons. Although the reference does not specifically recite the use of PLO as enhancing agent, it indicates the enhancing agent may include, and is not limited to the list indicated, which includes alcohols, surfactants, lecithin vesicles and others. Furthermore, the reference only excludes the combination of DMSO and PLO, it does not exclude the use of PLO alone (paragraph [0050]). Moreover, at the time of invention was made, it was known that PLO is a transdermal carrier (see Archer *et al.* (U.S. Patent 5,976,547, published November 2, 1999; Kryger, U.S. Patent 6,743,448, filed December 11, 2001). Therefore, in view of the teachings of Donovan and the art regarding PLO, it would have been

obvious to use the combination of botulinum toxin type A, saline and PLO for the claimed method.

Conclusion

4. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Patent Examiner

CHIH-MIN KAM
PATENT EXAMINER

CMK
May 17, 2006